

Serial No. 09/674,815
5836-01-AWZ (PC17416)

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-24 (cancelled).

Claim 25 (currently amended): A pharmaceutical composition comprising:

- (a) an α amino acid ~~for stabilizing the composition;~~
- ~~(b) an auxiliary agent which is different than water; and~~
- ~~(c)~~ (b) a 4-amino-3-substituted-butanoic acid derivative selected from the group consisting of gabapentin and/or pregabalin,

wherein the pharmaceutical composition is a liquid, and wherein as compared with a second composition that contains the same components as the pharmaceutical composition except for the absence of the α amino acid, after the pharmaceutical composition and the second composition each have been stored in a sealed container at 45 °C for 2 weeks the amount of lactam that is formed in the pharmaceutical composition relative to the initial amount of the 4-amino-3-substituted-butanoic acid derivative in the pharmaceutical composition is less than the amount of lactam that is formed in the second composition relative to the initial amount of the 4-amino-3-substituted-butanoic acid derivative in the second composition.

Claim 26 (previously presented): The composition of Claim 25 wherein the α -amino acid is one or more selected from:

- L-, D- and DL-forms of neutral α -amino acids;
- alkali salts, acid amides, alkyl-substituted derivatives of acid amides or alkyl esters of the L-, D- and DL-forms of acidic α -amino acids;
- acid addition salts or monoacylated derivatives of the L-, D- and DL-forms of basic α -amino acids;
- α,ω -diaminodicarboxylic acids; and

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acidic amino acid-basic amino acid adducts of the L-, D- and DL-forms of acidic α -amino acids and the L-, D- and DL-forms of basic α -amino acids.

Claim 27 (previously presented): The composition of Claim 25 wherein the α -amino acid is one or more selected from:

neutral α -amino acids consisting of glycine, phenylglycine, hydroxyphenylglycine, dihydroxyphenylglycine, L-alanine, hydroxy-L-alanine, L-leucine, hydroxy-L-leucine, dihydroxy-L-leucine, L-norleucine, methylene-L-norleucine, L-ketonorleucine, L-isoleucine, hydroxy-L-isoleucine, dihydroxy-L-isoleucine, L-valine, hydroxy-L-valine, L-isovaline, L-norvaline, hydroxy-L-norvaline, hydroxy-L-ketonorvaline, L-methionine, L-homomethionine, L-ethionine, L-threonine, acetyl-L-threonine, L-tryptophan, hydroxy-L-tryptophan, methyl-L-tryptophan, L-tyrosine, hydroxy-L-tyrosine, methyl-L-tyrosine, bromo-L-tyrosine, dibromo-L-tyrosine, 3,5-diiodo-L-tyrosine, acetyl-L-tyrosine, chloro-L-tyrosine, L-m-tyrosine, L-levodopa, L-methyldopa, L-thyroxine, L-serine, acetyl-L-serine, L-homoserine, acetyl-L-homoserine, ethyl-L-homoserine, propyl-L-homoserine, butyl-L-homoserine, L-cystine, L-homocystine, methyl-L-cysteine, allyl-L-cysteine, propyl-L-cysteine, L-phenylalanine, dihydro-L-phenylalanine, hydroxymethyl-L-phenylalanine, L-aminobutyric acid, L-aminoisobutyric acid, L-ketoaminobutyric acid, dichloro-L-aminobutyric acid, dihydroxy-L-aminobutyric acid, phenyl-L-aminobutyric acid, L-aminovaleric acid, L-aminohydroxyvaleric acid, dihydroxy-L-aminovaleric acid, L-aminoisovaleric acid, L-aminoheptanoic acid, methyl-L-aminoheptanoic acid, L-aminoheptanoic acid, L-aminoheptanoic acid and citrulline and the D- and DL-forms thereof;

acidic α -amino acids consisting of L-aspartic acid, L-glutamic acid, L-carbocysteine, L-aminoglutaric acid, L-aminosuccinic acid, L-aminoadipic acid, L-aminopimelic acid, hydroxy-L-aminopimelic acid, methyl-L-aspartic acid, hydroxy-L-aspartic acid, methyl-L-glutamic acid, methyl-hydroxy-L-glutamic acid, L-methyleneglutamic acid, hydroxy-L-glutamic acid, dihydroxy-L-glutamic acid and hydroxy-L-aminoadipic acid and the D- and DL-forms thereof;

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basic α -amino acids consisting of L-arginine, L-lysine, L-ornithine, L-canavanine, L-canaline, hydroxy-L-lysine, L-homoarginine, hydroxy-L-homoarginine, hydroxy-L-ornithine, L-diaminopropionic acid, L-diaminohexanoic acid, L-diaminobutyric acid, L-diaminovaleric acid, L-diaminoheptanoic acid, and L-diaminooctanoic acid and the D- and DL-forms thereof; and

α,ω -diaminodicarboxylic acids consisting of diaminosuccinic acid, diaminoglutaric acid, diaminoadipic acid and diaminopimelic acid;

provided that, when said α -amino acid is an adipic α -amino acid, it is used in the form of the corresponding alkali salt, acid amide, alkyl-substituted derivative of acid amide or alkyl ester thereof, or

when said α -amino acid is a basic α -amino acid, it is used in the form of the corresponding acid addition salt or monoacylated derivative thereof, or

said acidic α -amino acid and said basic α -amino acid are also used in the form of the corresponding acidic amino acid-basic amino acid adduct.

Claim 28 (previously presented): The composition of Claim 25 wherein a total amount of the α -amino acid is in the range of 0.001 - 80 moles per mole of the 4-amino-3-substituted-butanoic acid derivative.

Claim 29 (cancelled).

Claim 30 (cancelled).

Claim 31 (previously presented): The composition of Claim 25 wherein the 4-amino-3-substituted-butanoic acid derivative is gabapentin.

Claim 32 (withdrawn): The composition of Claim 25 wherein the 4-amino-3-substituted-butanoic acid derivative is pregabalin.

Claim 33 (previously presented): The composition of Claim 25 further comprising water.

Claim 34 (new): A pharmaceutical composition comprising:

(a) an α amino acid, and

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(b) a 4-amino-3-substituted-butanoic acid derivative selected from the group consisting of gabapentin and pregabalin,
wherein the pharmaceutical composition is a solid, and wherein as compared with a second composition that contains the same components as the pharmaceutical composition except for the absence of the α amino acid, after the pharmaceutical composition and the second composition each have been stored in a sealed container at 45 °C for 2 weeks the amount of lactam that is formed in the pharmaceutical composition relative to the initial amount of the 4-amino-3-substituted-butanoic acid derivative in the pharmaceutical composition is less than the amount of lactam that is formed in the second composition relative to the initial amount of the 4-amino-3-substituted-butanoic acid derivative in the second composition.

Claim 35 (new): The composition of Claim 34, wherein the α -amino acid is one or more selected from:

L-, D- and DL-forms of neutral α -amino acids;
alkali salts, acid amides, alkyl-substituted derivatives of acid amides or alkyl esters of the L-, D- and DL-forms of acidic α -amino acids;
acid addition salts or monoacylated derivatives of the L-, D- and DL-forms of basic α -amino acids;
 α,ω -diaminodicarboxylic acids; and
acidic amino acid-basic amino acid adducts of the L-, D- and DL-forms of acidic α -amino acids and the L-, D- and DL-forms of basic α -amino acids.

Claim 36 (new): The composition of Claim 34, wherein the α -amino acid is one or more selected from:

neutral α -amino acids consisting of glycine, phenylglycine, hydroxyphenylglycine, dihydroxyphenylglycine, L-alanine, hydroxy-L-alanine, L-leucine, hydroxy-L-leucine, dihydroxy-L-leucine, L-norleucine, methylene-L-norleucine, L-ketonorleucine, L-isoleucine, hydroxy-L-isoleucine, dihydroxy-L-isoleucine, L-valine, hydroxy-L-valine, L-isovaline, L-norvaline, hydroxy-L-norvaline, hydroxy-L-ketonorvaline, L-methionine, L-homomethionine, L-ethionine, L-threonine, acetyl-L-threonine, L-tryptophan, hydroxy-

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L-tryptophan, methyl-L-tryptophan, L-tyrosine, hydroxy-L-tyrosine, methyl-L-tyrosine, bromo-L-tyrosine, dibromo-L-tyrosine, 3,5-diiodo-L-tyrosine, acetyl-L-tyrosine, chloro-L-tyrosine, L-m-tyrosine, L-levodopa, L-methyldopa, L-thyroxine, L-serine, acetyl-L-serine, L-homoserine, acetyl-L-homoserine, ethyl-L-homoserine, propyl-L-homoserine, butyl-L-homoserine, L-cystine, L-homocystine, methyl-L-cysteine, allyl-L-cysteine, propyl-L-cysteine, L-phenylalanine, dihydro-L-phenylalanine, hydroxymethyl-L-phenylalanine, L-aminobutyric acid, L-aminoisobutyric acid, L-ketoaminobutyric acid, dichloro-L-aminobutyric acid, dihydroxy-L-aminobutyric acid, phenyl-L-aminobutyric acid, L-aminovaleric acid, L-aminohydroxyvaleric acid, dihydroxy-L-aminovaleric acid, L-aminoisovaleric acid, L-aminohexanoic acid, methyl-L-aminohexanoic acid, L-aminoheptanoic acid, L-aminooctanoic acid and citrulline and the D- and DL-forms thereof;

acidic α -amino acids consisting of L-aspartic acid, L-glutamic acid, L-carbocysteine, L-aminoglutaric acid, L-aminosuccinic acid, L-aminoadipic acid, L-aminopimelic acid, hydroxy-L-aminopimelic acid, methyl-L-aspartic acid, hydroxy-L-aspartic acid, methyl-L-glutamic acid, methyl-hydroxy-L-glutamic acid, L-methyleneglutamic acid, hydroxy-L-glutamic acid, dihydroxy-L-glutamic acid and hydroxy-L-aminoadipic acid and the D- and DL-forms thereof;

basic α -amino acids consisting of L-arginine, L-lysine, L-ornithine, L-canavanine, L-canaline, hydroxy-L-lysine, L-homoarginine, hydroxy-L-homoarginine, hydroxy-L-ornithine, L-diaminopropionic acid, L-diaminohexanoic acid, L-diaminobutyric acid, L-diaminovaleric acid, L-diaminoheptanoic acid, and L-diaminooctanoic acid and the D- and DL-forms thereof; and

α,ω -diaminodicarboxylic acids consisting of diaminosuccinic acid, diaminoglutaric acid, diaminoadipic acid and diaminopimelic acid;

provided that, when said α -amino acid is an adipic α -amino acid, it is used in the form of the corresponding alkali salt, acid amide, alkyl-substituted derivative of acid amide or alkyl ester thereof, or

when said α -amino acid is a basic α -amino acid, it is used in the form of the corresponding acid addition salt or monoacylated derivative thereof, or

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said acidic α -amino acid and said basic α -amino acid are also used in the form of the corresponding acidic amino acid-basic amino acid adduct.

Claim 37 (new): The composition of Claim 34, wherein a total amount of the α -amino acid is in the range of 0.001 - 80 moles per mole of the 4-amino-3-substituted-butanoic acid derivative.

Claim 38 (new): The composition of Claim 34, wherein the 4-amino-3-substituted-butanoic acid derivative is gabapentin.

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